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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,172

09/15/2006

Harold E. Cutler

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8804

85688

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EXAMINER

STUART, COLIN W

ART UNIT

PAPER NUMBER

3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,172	Applicant(s) CUTLER, HAROLD E.	
	Examiner COLIN STUART	Art Unit 4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-12,14-17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-12,14-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is responsive to a preliminary amendment filed 5/30/07. As directed by the amendment, claims 1, 4, 6, 8, 9, 11, 12, and 14-16 were amended, claims 2, 7, 13, 18, and 19 were cancelled, and claim 20 was added. Thus, claims 1, 3-6, 8-12, 14-17, and 20 are pending in this application.

Drawings

2. The drawings are objected to because figures 2, and 4-5 do not have connection lines showing how the separate elements are connected together. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

Art Unit: 4177

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "54" has been used to designate both the tongue member and the palate member. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6, and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Pivovarov (2004/0211430).

In regards to claim 1, Pivovarov teaches an oral device which includes a mouthpiece member (18 & 32), a tube member (16) and an attachment member ("connection locations for attachment of a strap (not shown)" para. 0030). The Pivovarov's device is soft, resilient, and adapted to fit the contours of the teeth of a wearer (see para. 0027 ln. 12 and Fig. 9). Fig. 1 shows that the tube member (16) is affixed at a first end to the mouthpiece member (18 & 32) and extends outwards toward the soft palate of the wearer as well as functioning to maintain upward pressure against the soft palate towards the rear of the oral cavity of the patient. The attachment member is attached to the mouthpiece member (18 & 32) at opposing apertures (36) (see Fig. 1) and the tube member defines an opening allowing for the transfer of air without the collapse of the soft palate (see Figs. 1-9).

In regards to claim 6, Pivovarov teaches an oral device which also includes a soft palate member (12A) which extends from a second end of the tube member (16) and curves upwards toward the soft palate to maintain upward pressure.

In regards to claim 11, the tube member (Pivovarov 16) of the Pivovarov's device does not extend past the teeth of the wearer (see Fig. 9) and allows for air to be dispersed throughout the whole oral cavity of the wearer.

In regards to claim 12, Pivovarov teaches an oral device which also includes a tongue member (12B) which extends from a second end of the tube member (16) and curves downward maintains contact with the tongue of the wearer.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pivovarov (2004/0211430) as applied to claim 1 above, and further in view of Dennis (6,517,549).

In regards to claim 3, the Pivovarov's device teaches all the limitations as discussed above; however, is silent to providing a cushion member on the second end of the tube member. Dennis teaches a mouthpiece assembly which includes a cushion member (Dennis 160) disposed along a tube member (Dennis 122) (see Fig. 1 of Dennis). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pivovarov's device to include a cushion member (Dennis 160), as taught by Dennis, at the second end of the tube member (Pivovarov 16) to increase the comfort of the device as well as prevent possible damage to soft tissue created by the plastic material.

In regards to claims 8 and 14, note that one of ordinary skill in the art at the time the invention was made would recognize that an end of the soft palate member and tube member interface with each other and extending the length of the cushion

Art Unit: 4177

member, as taught by Dennis, to cover the end of the soft palate member would have been obvious to increase the comfort of the device.

7. Claims 4, 9, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pivovarov (2004/0211430) as applied to claim 1 above, and further in view of Pivovarov (6,675,804).

In regards to claims 4, 9, 15, and 16, the Pivovarov's device teaches all the limitations as discussed above; however, is silent to providing that the tube member (claim 4), palate member (claim 9), or the palate member and tongue member (claims 15 & 16) comprise an adjustable length to span the distance between the mouth and soft palate of the wearer. Pivovarov '804 teaches an oral device in which a "connector 16 is formed of resilient material shaped in an undulating sine wave pattern that allows for ... comfort and adjustability" (Pivovarov '804 col. 3 ln. 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Pivovarov's tube member (Pivovarov 16), palate member (Pivovarov 12A), or the palate member (Pivovarov 12A) and tongue member (Pivovarov 12B) with the undulating sine wave pattern for adjustability as taught by Pivovarov '804 because the adjustability feature provides ability for a more comfortable fit with the wearer. Note that including the undulating sine wave adjustability feature to the soft palate member would engage and lift the palate in the pharyngeal area of the wearer. Furthermore adding the adjustable feature to the tongue member would make it capable of extending along the

Art Unit: 4177

top of the tongue of the wearer as the undulating sine wave adjustable feature allows for angular adjustment as well as radial or lengthwise adjustment.

8. Claims 5, 10, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pivovarov (2004/0211430) as applied to claim 1 above, and further in view of Jackson (5,174,284).

In regards to claims 5, 10, and 17, the Pivovarov's device teaches all the limitations as discussed above; however, is silent to teaching the attachment member being made out of a resilient material. Jackson teaches an oral device which discloses attachment of "an elastic headband, not shown" (col. 2 ln. 61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment member of Pivovarov's reference to be made of a resilient elastic material as taught by Jackson in order to increase the comfort of the device and ensure a proper fit.

In regards to claim 20, the adjustable tongue member of the modified Pivovarov's device is capable of following any curvature of the tongue including the downward curvature so as to control the movement of the tongue of the wearer.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art:

Art Unit: 4177

Meah (6,257,238), Robertson et al. (2003/0089371), and Wright (2006/0207597) are all related to oral devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 4177

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771